

Citation:

Wylie-Rosett J, Swencionis C, Ginsberg M, Cimino C, Wassertheil-Smoller S, Caban A, Segal-Isaacson CJ, Martin T, Lewis J. Computerized weight loss intervention optimizes staff time: the clinical and cost results of a controlled clinical trial conducted in a managed care setting. *J Am Diet Assoc.* 2001; 101:1155-1162.

PubMed ID: [11678486](#)

Study Design:

RCT

Class:

A - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To evaluate the costs and effects of incremental components of a weight-loss program.

Inclusion Criteria:

1. BMI >25 (or BMI=24 + 1 cardiovascular risk factor)
2. Willingness to follow the study protocol

Exclusion Criteria:

1. Plans to move beyond commuting distance in the next 12 months.
2. Medical conditions that would interfere with study participation
3. Unwillingness to follow the study protocol.

Description of Study Protocol:**Recruitment:**

Subjects were recruited from the HMO and the surrounding community by newspaper articles, flyers, posters, local media news coverage via cable TV and newspapers.

Design: Randomized Controlled Trial. Cognitive behavioral approach for tailoring goals, including both lifestyle and behavioral modification was used. The intervention materials addressed motivation and behavioral goals based on an individualized needs assessment and the principles of the Transtheoretical Model of Behavioral Change.

Blinding Used (if applicable): Not applicable.

Intervention: 3 levels of intervention were used (workbook, workbook + computer, workbook + computer + staff consultation).

Statistical Analysis:

Power calculation done to determine the number of subjects needed for statistical significance. Study endpoints were analyzed using analysis of variance for normally distributed variables and analysis of covariance to control for any baseline differences. Regression and correlation analysis assessed the relationship between weight loss and other variables. Mean is reported \pm SD.

Data Collection Summary:

Timing of Measurements:

Data collected at baseline and 1 yr: anthropometrics, body composition, fasting lipids and glucose, physical activity as determined by the Paffenbarger questionnaire, dietary intake as determined by the Block FFQ and medical history by chart review.

Dependent Variables:

- Weight,
- lipid profile,
- plasma glucose,
- blood pressure,
- intervention costs,
- dietary intake,
- physical activity

Independent Variables:

- cost data: labor costs as determined by salary + benefits and time spent, supplies and cost of computer network services.
- Interventions:
 - Workbook: do-it-yourself in which subjects completed self-help sheets.
 - Computer: utilized a fileserver + 5 multimedia computers with touch screens located at the HMO facility; software designed to guide subjects to use the workbook and tailor behavioral goals based on prior computer use and addressed nutrition, fitness and psychobehavioral content. Instruments used to tailor goals were: Block fat screener, intake compared to the Food Guide Pyramid, Paffenbarger self-reported physical activity, Sallis dietary and exercise self-efficacy scales, and an instrument to assess barriers to lifestyle change.
 - Staff consultation: 6 closed-group workshop sessions that focused on specific activities and assignments in the workbook and encouraged use of the computer to identify problems and issues. Also included up to 18 telephone or face-to-face consultations with an RD or cognitive behavioral therapist.

Description of Actual Data Sample:

Initial N: 1,560 potential subjects were invited to an orientation seminar; 1,041 attended the seminar and completed a brief survey, 919 agreed to participate and 722 completed computerized baseline questionnaires and 588 completed randomization to the study.

Attrition: Of the 588, 81% completed the 12 month study; dropout rates were as follows: workbook: 16%, workbook + computer: 22%, workbook + computer + staff consultation: 17%. There were no differences among those who dropped out and those who remained in the study at baseline. 82.3% were female.

Age: mean 52.2 yrs

Ethnicity: 83% were white

Other Relevant Demographics:

- 84% > 1 yr of college education

Anthropometrics:

- BMI 35.6 ± 6.5
- T-chol, mmol/L 5.70 ± 42.1
- LDL-chol, mmol/L 3.70 ± 35.4
- TG, mmol/L 1.59 ± 78.4
- Glucose, mmol/L 5.59 ± 33.8
- Blood pressure, mmHg: Systolic 129.0 ± 16.5 , Diastolic 83.6 ± 8.9

Location: Conducted at an HMO on the Albert Einstein College of Medicine Long Island campus, NY.

Summary of Results:

1 Year Lifestyle and Physiological Changes by
Intervention Group

Parameter	workbook only	workbook + computer	workbook + computer + staff intervention	P value
n	97	183	194	
weight loss (lb)	2.2 ± 1.26	4.7 ± 1.02	7.4 ± 1.15	<0.003
BMI (kg/m ²)	-0.4 ± 0.21	-0.8 ± 0.17	-1.2 ± 0.19	<0.003
% body fat	-0.001 ± 0.441	-0.161 ± 0.287	-1.233 ± 0.294	<0.001

% weight loss	0.9 ± 0.54	2.2 ± 0.48	3.5 ± 0.49	<0.002
---------------	------------	------------	------------	--------

Other Findings:

- Those who completed the baseline questionnaires had a greater proportion of people with diabetes (10.9% vs. 4.8%, $P=0.04$) and who felt comfortable using the computer (77.7% vs. 71.49%, $P=0.02$).
- The mean energy intake and % fat decreased and the number of blocks walked increased compared to baseline in all 3 intervention groups ($P<0.01$).
- Weight loss was significantly different among the treatment groups.
- Across all groups, correlates of weight loss were: decrease in energy ($r=0.18$, $P=0.0001$), decrease % energy from fat ($r=0.26$, $P=0.0001$) and increase in the number of blocks walked ($r=0.16$, $P=0.002$).
- There were no differences among the treatment groups for the metabolic parameters or blood pressure. However, the most intensive group (+staff intervention) had a significant increase in HDL cholesterol and decrease in blood pressure ($P<0.01$).
- For the pooled intervention groups, weight loss correlated with a decrease in blood pressure (systolic, $r=0.16$, $P=0.0007$; diastolic, $r=0.19$, $P=0.0001$) and a decrease in fasting blood glucose ($r=0.14$, $P=0.004$).
- Intervention variables that correlated with weight loss included: more self-monitoring ($r=0.25$, $P=0.0001$), increase in attendance at in staff consultation group meetings ($r=0.22$, $P=0.002$), increase frequency of computer sessions ($r=0.24$, $P=0.0001$), feeling successful with self-monitoring ($r=0.25$, $P=0.0001$) and achieving more computer dietary goals ($r=0.13$, $P=0.02$).
- The cost of the 3 different interventions for each participant was: 1. Workbook: \$ 12.33, 2. Workbook + computer: \$ 41.99, 3. Workbook + computer + staff: \$133.74

Author Conclusion:

In a weight-loss program, computers can facilitate selecting behavioral change goals. More frequent usage resulted in greater weight loss. Staff counseling to augment the computer intervention achieved the most weight loss.

More effort is needed for preventive services related to controlling the adverse effects of obesity. RDs and other health professionals should consider using computer-based communications to maintain frequent contact, promote self-monitoring, and tailor behavioral goals.

Computer-based communication strategies can be readily combined with other approaches. The cost/participant in each of the 3 interventions was quite modest. HMOs could potentially incorporate all 3 options as preventive health services. Patients could opt for an approach based on availability and personal preference for learning method and time.

Reviewer Comments:

Well done study comparing different interventions for weight loss in individuals with BMIs >30.

One of few RCT evaluating weight loss with a duration of 1 yr.

Although some of the outcome measures were not different by study group, for all participants, weight loss was correlated with improvements in metabolic measures and blood pressure.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

- | | | |
|----|---|-----|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

Validity Questions

- | | | |
|------|---|-----|
| 1. | Was the research question clearly stated? | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| 1.3. | Were the target population and setting specified? | Yes |
| 2. | Was the selection of study subjects/patients free from bias? | Yes |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups? | Yes |
| 2.3. | Were health, demographics, and other characteristics of subjects described? | Yes |
| 2.4. | Were the subjects/patients a representative sample of the relevant population? | Yes |
| 3. | Were study groups comparable? | Yes |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | Yes |
| 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? | Yes |
| 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.) | Yes |

3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blinding used to prevent introduction of bias?	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A

6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes

8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

Copyright American Dietetic Association (ADA).